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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/934,297	08/21/2001	Jennifer E. Van Eyk	PTQ-0037	8294
26259	7590	03/25/2004	EXAMINER	
LICATLA & TYRRELL P.C.			LAM, ANN Y	
66 E. MAIN STREET			ART UNIT	
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1641

DATE MAILED: 03/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/934,297	Applicant(s) VAN EYK ET AL.	
	Examiner Ann Y. Lam	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on December 1, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 29-56 is/are pending in the application.
- 4a) Of the above claim(s) 9-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 29-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/21/04, 2/25/02</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Claims 9-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in amendment filed December 1, 2003.

Applicant's election with traverse of the restriction requirement mailed September 29, 2003 is acknowledged. The traversal is on the ground(s) that the groups are not independent or distinct, with independent meaning there is no disclosed relationship between the subjects and distinct meaning the subjects are patentable over each other. This is not found persuasive because the invention as claimed in the independent claims are separate inventions and are patentable over each other. Moreover, there is a serious burden on the Examiner to the extent that a search for prior art for one invention would not necessarily reveal any art relating to the other inventions since the claims require different elements or steps.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 2, 5, 8, 33, 34, 35, 37, 38, 42, 45, 48, 49, 50, 51, 53, 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Figard, 5,616,460, in view of Pilotti et al., 5,994,507.

Figard discloses the invention substantially as claimed.

More specifically, Figard discloses a method of separating a mixture of proteins in a biological sample (column 5, lines 6-9, and 13-15) comprising:

(a) substantially denaturing protein in said sample (column 5, lines 6-9 and 13-15 and column 5, lines 31-35), wherein the sample is mixed with a solution comprising a sulfhydryl reducing agent (dithioerythritol, column 4, lines 41-42; and lines 48-52), an anionic detergent (sodium dodecyl sulfate, column 5, lines 24-25), and at least one detergent selected from the group consisting of an ionic detergent (column 5, line 17), a non-ionic detergent (column 5, line 17) and a zwitterionic detergent (CHAPS, column 5, line 26), at concentrations sufficient to substantially denature albumin in the mixture (column 5, lines 6-9 and 13-15 and lines 31-35); and

(b) subjecting the mixture of biological sample and solution to a separation technique to separate proteins in the mixture (column 1, lines 8-9, lines 29-50, column 2, lines 25-29, and column 6, lines 40-41).

Figard discloses that the biological detergents reduce non-specific binding of antibodies other than the analyte antibodies to the microparticles of the assay in order to minimize or eliminate false positive results. The biological detergents reduce the incidence of such binding caused by nonpolar or hydrophobic interaction (column 5, lines 6-15).

However, Figard does not disclose that the detergents are used reduce non-specific binding of albumin.

Pilotti teaches a method of removing albumin from liquid samples for purification of albumin and further processing of the liquid samples in the absence of albumin (column 1, lines 10-14).

Pilotti further teaches that albumin binds to ligands through interactions such as hydrophobic interactions (column 1, lines 46-57.) It would have been obvious to one of ordinary skill in the art that the Figard method can be modified to reduce non-specific binding of albumin as taught by Pilotti since Pilotti teaches that albumin also non-specifically binds through hydrophobic interactions and that it is desirable to remove albumin from samples for purification of albumin and further processing of the liquid samples.

As to claim 2, characterizing the separated proteins is disclosed (column 1, lines 30-55 and column 6, lines 40-41).

As to claim 5, heating the mixture from step (a) prior to separation in step (b) is disclosed (column 2, lines 53-57, column 3, lines 15-18, column 7, lines 14-18, column 8, lines 24-26).

As to claim 8, the anionic detergent is sodium dodecyl sulfate (column 5, lines 24-25).

As to claim 33, diluting said mixture of sample and solution prior to said separation step is disclosed (column 6, lines 55-56).

As to claim 34, said separation technique is affinity-based (column 1, lines 29-49).

As to claim 35, said separation technique comprises chromatography (column 1, lines 36-49).

As to claim 37, the protein of said mixture of proteins is contacted with an antibody (column 1, lines 29-49).

As to claim 38, the protein of said mixture is contacted with a first antibody, and said first antibody is contacted with a second antibody to the first antibody (column 1, lines 42-49).

As to claim 42, said characterizing step comprises colorimetric detection (column 1, lines 48-49).

As to claim 45, said characterizing step comprises detecting enzyme activity (column 1, lines 59-60).

As to claim 48, Figard teaches that the effective concentrations of the biological detergent vary and discloses a possible range (see column 5, lines 31-34). Figard does

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not specifically teach that the sodium dodecyl sulfate is present in a concentration of from about 5 mM to about 150 mM. However, the range of concentration to achieve optimum results (i.e., a maximum reduction in the incidence of such binding caused by nonpolar or hydrophobic interaction) would require only routine experimentation and would thus be obvious. It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

As to claim 49, said zwitterionic detergent is CHAPS (column 5, line 26).

As to claim 50, Figard teaches that the effective concentrations of the biological detergent vary and discloses a possible range (see column 5, lines 31-34). Figard does not specifically teach that the detergent CHAPS is present in a concentration of from about of from about 5 mM to about 50 mM. However, the range of concentration that would achieve the optimum result (i.e., a maximum reduction in the incidence of such binding caused by nonpolar or hydrophobic interaction) would require only routine experimentation and would thus be obvious. It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

As to claim 51, said non-ionic detergent is Tween (column 5, line 20).

As to claim 53, said sulfhydryl reducing agent is dithioerythritol (column 4, line 42).

As to claim 54, Figard teaches that the effective concentrations of the biological detergent vary and discloses a possible range (see column 5, lines 31-34). Figard does

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not specifically teach that the detergent dithioerythritol is present in a concentration of from about of from about 5 mM to about 150 mM. However, the range of concentration that would achieve the optimum result (i.e., a maximum reduction in the incidence of such binding caused by nonpolar or hydrophobic interaction) would require only routine experimentation and thus would be obvious to one of ordinary skill in the art. It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

3. Claims 3, 4, 7, 29, 30-32, 36, 39, 40, 41, 43 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Figard, 5,616,460, in view of Pilotti et al., 5,994,507, as applied to claim 1, and further in view of Schwartz et al., 6,020,139.

Figard in view of Pilotti disclose the invention substantially as claimed (see above), except for the sample being serum, plasma, urine, amniotic fluid, cerebrospinal fluid, or the separation technique utilizes SDS-PAGE or HPLC, or the characterizing step identifies a protein associated with myocardial or skeletal damage or comprises fluorescence detection or radiodetection or radiographic film.

Schwartz discloses diagnostic assays for the detection of disease states and conditions (see abstract), the assay involving antibodies. It would have been obvious to modify the Figard-in-view-of-Pilotti method of preventing non-specific binding of albumin

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in assays, by using the particular assay taught by Schwartz as would be desirable for the detection of disease states and conditions as taught by Schwartz.

As to claim 3, Schwartz discloses that the separation of proteins is by Western blot (column 63, line 19).

As to claim 4, Schwartz discloses that the sample comprises serum (column 12, line 9).

As to claim 7, the separation technique is performed using SDS-PAGE (column 63, line 17).

As to claim 29, the sample comprises plasma (column 12, line 9).

As to claim 30, the sample comprises urine (column 12, line 10).

As to claim 31, the sample comprises amniotic fluid (column 12, lines 10-11).

As to claim 32, the sample comprises cerebrospinal fluid (column 12, line 10).

As to claim 36, said chromatography is high performance liquid chromatography (HPLC) (column 41, line 7).

As to claim 39, said characterizing step identifies at least one protein associated with myocardial damage (column 38, lines 6-9 and 43).

As to claim 40, said characterizing step identifies at least one protein associated with skeletal muscle damage (column 38, lines 6-9 and 43).

As to claim 41, said characterizing step comprises fluorescence detection (column 10, line 34).

As to claims 43 and 44, said characterizing step comprises radiodetection and detection using radiographic film (column 5, line 33).

4. Claims 6, 46, 47, 55 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Figard, 5,616,460, in view of Pilotti et al., 5,994,507, as applied to claim 1, and further in view of Rubenstein et al., 4,376,825.

Figard in view of Pilotti disclose the invention substantially as claimed (see above), except for the mixture being boiled, and the enzyme activity being horseradish peroxidase activity or alkaline phosphatase activity, and the solution containing urea.

Rubenstein discloses an assay involving antibodies (column 6, lines 12-24) and blood proteins found in blood (column 7, line 57, column 8, lines 45-54). It would have been obvious that Figard-in-view-of-Pilotti method of preventing non-specific binding of albumin in assays can be further modified by using the particular Rubenstein assay as would be desirable to determine the presence of a specific organic material as taught by Rubenstein.

As to claim 6, the mixture is boiled (column 57, line 29).

As to claim 46, said enzyme activity is horseradish peroxidase activity (column 37, line 3).

As to claim 47, said enzyme activity is alkaline phosphatase activity (column 50, line 45).

As to claim 55, said solution further comprises urea (column 31, line 28, column 62, line 3).

As to claim 56, the concentration of urea that would achieve the optimum result (would be discovered through routine experimentation. It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

5. Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Figard, 5,616,460, in view of Pilotti et al., 5,994,507, and further in view of Aitman et al., 6,322,976.

Figard in view of Pilotti disclose the invention substantially as claimed (see above), except for the non-ionic detergent being Ipegal CA-360 in an amount of from about 0.2% to about 4%.

Aitman discloses an assay involving antibodies wherein a non-ionic detergent Ipegal-360 is used. It would have been obvious to modify the Figard-in-view-of-Pilotti method of preventing non-specific binding of albumin in assays using Ipegal CA-360 as an alternative to the non-ionic detergents listed in Figard, since Aitman discloses Ipegal CA-360 as a known non-ionic detergent.

As to the particular Ipegal CA-360 concentration claimed, the concentration that would achieve the optimum result (i.e., a maximum reduction in the incidence of such binding caused by nonpolar or hydrophobic interaction) would have been discovered by routine experimentation and thus would have been obvious. It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the

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optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Vaughan et al., 4,654,419, discloses the non-specific binding property of albumin. Murray et al., 4,563,423, Switchenko et al., 5,840,508, and Enomoto et al., 5,508,202, all disclose a solution containing the detergents above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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